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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,828	02/17/2004	Sudhir R. Brahmbhatt	22-234	9145

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EXAMINER	
WARE, DEBORAH K	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,828	BRAHMBHATT, SUDHIR R.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2/9/06* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6 and 25-26 are presented for reconsideration on the merits.

Interview Summary

The interview summary record of February 9, 2006, is enclosed. The formal written reply which included the substance of this interview in accordance with MPEP 713.04 was received on February 13, 2006, and hence no further reply is necessary as Applicants have met their obligation for this section of the MPEP with respect to the interview summary record submitted herewith.

Response to Amendment

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The amendment filed June 14, 2006, and arguments therewith have been received and entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added claim language

"wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel" is not supported by the instantly filed disclosure.

Applicants have provided no supportive evidence wherein the examiner may glean support for this newly added claim language based upon the originally filed disclosure. Therefore, the language is deemed to be new matter and either support for the language needs to be provided to the examiner by pointing out to her the places in the original disclosure by page and line numbers and sections as needed to show the support for the language or the language is required to be deleted.

There is a preponderance of evidence that a person of skill in the art would not recognize in Applicant's disclosure the newly described claimed subject matter now defined by claims because Applicants have provided no guidance in their specification that continuous injecting of oxygen is carried out or how it is carried out. Further, Applicant has not provided any points of reference wherein the examiner can refer to for their support. Hence, it is suggested that the new matter be deleted.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Cheng (US 2003/0080446 A1) (A) or Cheng (US PAT NO 5,985,652) (C) or Cheng (US PAT NO 5,798,254) (B) in view of the previous cited EP 0 341 878 A1 and cited of record in last office action of April 12, 2006, set forth below.

Claims are drawn to a fermentation process wherein the improvement comprises injecting a stream of substantially pure oxygen into a vessel during fermentation

wherein it is the sole reactive gas, from any source external to the vessel, and it is moved through the vessel solely due to pressure in an oxygen supply. Additionally the claims are drawn to the stream as the only gas that is injected continuously into the vessel.

Cheng (A) teaches a fermentation process wherein the improvement comprises injecting a stream of pure oxygen and air into a vessel during fermentation and it is moved through the vessel solely due to pressure in an oxygen supply. Note page 2, column 2, paragraph [0028], all lines and the abstract.

Cheng (C) teaches a fermentation process wherein the improvement comprises injecting a stream of pure oxygen and air into a vessel during fermentation and it is moved through the vessel solely due to pressure in an oxygen supply. See the abstract and column 4, lines 9-40.

Cheng (B) teaches a fermentation process wherein the improvement comprises injecting a stream of pure oxygen and air into a vessel during fermentation and it is moved through the vessel solely due to pressure in an oxygen supply. Note abstract and columns 3, line 26 and 46-47 and column 4, lines 1-18.

EP, cited of record, teaches at page 3, lines 28-35 that the fermenter is injected with an inert gas and substantially pure oxygen, note specifically page 3, lines 5-6 and line 29. Furthermore, at page 5, Table of example 2, it is shown that increased efficiency of the vessel (note at page 5, line 31, 96% utilization of the vessel) and less agitation is needed during the fermentation process (note at page 5, line 160 rpm

agitation rate for pumped loop versus 350 rpm pump loop shut off) when a continuous supply of oxygen is provided (i.e. pumped loop operation).

The claims differ from the cited Cheng references in that oxygen is not the sole reactive gas and continuous injection thereof into the vessel is not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the air in each of the Cheng references with the inert gas disclosed by EP to provide for continuous injection of pure oxygen into the fermenter as the sole reactive gas because the inert gas of EP would have been expected to mix but not react with the secondary gas disclosed by each of the Cheng references, and increased efficiency obtained thereby its continuous injection into the fermenter as disclosed by EP would have been an obvious modification. No reaction of pure oxygen with the inert gas would have been expected. The pure oxygen is shown in each of the cited Cheng references to move through the vessel soley due to pressure in the oxygen.

The continuous injection of the oxygen would have been expected to be from any source external to the vessel in order to inject it into the vessel, there being some means expected to provide for the pure oxygen supply thereto. Each of the cited references teach mechanically agitating, measuring oxygen concentration and adjusting a flow of oxygen into the fermenter. Furthemore, EP clearly shows the increased efficiency for fermentation process by providing for a continuous supply of oxygen. There are no unobvious and unexpected results obtained by continuously injecting oxygen into the fermenter because EP clearly shows the improvements. To

continuously inject a fermenter with substantially pure oxygen is an obvious modification well within the purview of an ordinary artisan.

A continuous system is clearly contemplated by the cited prior art, as is continuously injecting oxygen into a fermenter. Further, the fermenter systems are also contemplated to perform without agitation as well. Measuring continuously is clearly within the skill of an ordinary artisan. A blower nor a compressor are disclosed by the Cheng references. Also to perform the injecting step without mixing of the oxygen with liquid is clearly an obvious modification of the cited prior art. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed June June 14, 2006, have been fully considered but they are not persuasive. The argument at page 6 referring to figure 2, relating to an air-lifted fermenter, is noted. However, at page 5, lines 5-11, of the instantly filed specification it is clearly disclosed that in the case of a mechanically-agitated fermenter, the oxygen is the only gas external to the vessel, that is directed into the vessel. The claims recite that "oxygen is the sole reactive gas, from any source external to the vessel that is injected into the vessel". Hence the claims do not read specifically, on the embodiment of Figure 2, relating to an air-lifted fermenter, and Applicant's arguments are not deemed persuasive.

Further, whether or not nitrogen is injected only when needed or continuously or not injected is irrelevant to the instant claimed subject matter because the claims do not

recite this limitation. Therefore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., embodiment of figure 2, notably nitrogen being non-participatory in the fermentation, needed only for removing carbon dioxide, etc.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, as the above rejection explains it would have been obvious to one of skill in the art to inject continuously substantially pure oxygen into a vessel to improve efficiency of oxygen absorption as taught by the EP reference.

EP also teaches that the use of substantially pure oxygen to aerate the culture enables the proportion of the main body of the fermenter which is occupied by culture to be increased as compared with a conventional fermentation process using air to aerate the culture; and this is because the volume of gas supplied to the culture for its aeration is reduced since no inert nitrogen is added with the oxygen, note page 3, lines 6-9. Therefore, when taking the teachings in combination one of ordinary skill in the art would have been motivated to continuously inject substantially pure oxygen as the sole reactive gas or only gas as claimed herein. Further, Applicant should note that the

claims do not necessarily omit additional steps of injecting other gases as needed, because the claim language is open to other improvements as needed. Therefore, the claims are rejected as being *prima facie* obvious over the cited prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the record. Therefore, the claims are properly rejected.

Other art is cited to further show the state of the art, note enclosed PTO-892 Form.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware
August 19, 2006

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651